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10/516,389	06/09/2005	Stanley Frinak	0256.00004	4725
<div>Amy E Rinaldo Kohn &amp; Associates Suite 410 30500 Northwestern Highway Farmington Hills, MI 48334</div>				
			EXAMINER	
			SAIDI, AZADEH	
			ART UNIT	PAPER NUMBER
			3709	
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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

## Office Action Summary

Application No.

10/516,389

Applicant(s)

FRINAK ET AL.

Examiner

Anita Saidi

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— The MAILING DATE of this communication appears on the cover sheet with the correspondence address —

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 15 February 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-25 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-25 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 30 November 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_.

## **DETAILED ACTION**

### ***Claim Rejections - 35 USC § 112***

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2. Claims 1-9, 15-16 & 17-23 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. The analyzing means in the specifications has been defined as either a dialysis machine or an equation, but no structure has been associated to it. As for claims 17-23, no structure has been associated with the algorithm, and the nature and body of the algorithm has not been claimed.

Therefore the use and make of the invention is not clear to the examiner.

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 1-9, 15-16 & 17-23 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.
5. Claims 2-3 recites the limitation "analyzing means" in line 2. There is insufficient antecedent basis for this limitation in the claim.

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Based on the invocation of 112, 6<sup>th</sup> paragraph (see below), it is recommended to change "analyzing means" to - - means for analyzing- -.

**35 USC, § 112, 6<sup>TH</sup> Paragraph**

6. A claim limitation will invoke 35 U.S.C. 112, sixth paragraph, if it meets the following 3-prong analysis:

- (A) The claim limitations must use the phrase "means for " or "step for "
- (B) The "means for " or "step for " must be modified by functional language;  
and
- (C) The phrase "means for " or "step for " must not be modified by sufficient structure, material or acts for achieving the specified function.

Where means plus function language is used to define the characteristics of a machine or manufacture invention, such language must be interpreted to read on only the structures or materials disclosed in the specification and "equivalents thereof" that correspond to the recited function.

Claims 1-16 & 24-25 invoke 35 U.S.C. 112, sixth paragraph, as they meet the three prong tests above; therefore the following claim limitations are being treated as invoking 35 U.S.C. 112, sixth paragraph.

For art rejection purposes the claim limitations:

In ref to claims 1 & 24:

- a. Means for analyzing blood pressure

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Have been interpreted as covering the following respective corresponding structures described in the specification:

- a. A computer program or a dialysis machine

### ***Claim Interpretations***

7. In light of 112, 6<sup>th</sup> paragraph invocation and the associated 112, 2<sup>nd</sup> paragraph indefiniteness above, the claims are rejected on prior art as best understood.

**Note:** In view of the aforementioned, an absence of a prior art rejection of any claim(s) should not be taken as an indication of allowable subject matter unless otherwise indicated.

### ***“For use”, “Adapted to,” “Adapted for,” “Wherein,” and “Whereby”***

#### ***Clauses***

8. The subject matter of a properly construed claim is defined by the terms that limit its scope. Claim scope is not limited by claim language that suggests or makes optional but does not require steps to be performed, or by claim language that does not limit a claim to a Particular structure. However, examples of claim language, although not exhaustive, that may raise a question as to the limiting effect of the language in a claim are:

- (A) “Adapted to” or “adapted for” clauses;
- (B) “Wherein” clauses; and

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(C) "Whereby" clauses.

It should be noted that claims 2-9 uses the transitional phrase, "wherein" & "For use", which describes the functional capability of the provided information and does not add any additional limitation to claim 1.

***Claim Rejections - 35 USC § 101***

9. 35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

10. Claims 1-9, 15-16 and 17-23 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter.

On October 26, 2005, the USPTO published Interim Guidelines for Examination of Patent Applications for Patent Subject Matter Eligibility. See:

[http://www.uspto.gov/web/offices/pac/dapp/opla/preognotice/guidelines101\\_20051026.p](http://www.uspto.gov/web/offices/pac/dapp/opla/preognotice/guidelines101_20051026.p)

df

This guideline details a procedure for determining patent eligible subject matter. As to claims 1-9, 15-16 and 17-23, the first step in this process is whether the claims fall within one of enumerated categories. In the immediate application, the claim is drawn to a process - a "method of sensing pressure" - and meets this step. However, the analysis does not end here. The next step is whether a judicial exception (abstract ideas, laws of nature, natural phenomenon) is provided in the claim. In the immediate application, claim 1 clearly includes one of the judicial exceptions in that "computing stiffness and deriving an index" is nothing more than an abstract idea. While abstract ideas alone are not eligible, the claim as a whole must be analyzed to determine whether it is for a particular application of the abstract idea. For claims including such excluded subject matter to be eligible, the

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claim must be for a practical application of the abstract idea, law of nature, or natural phenomena. To satisfy the requirement of a practical application, the claimed invention must:

**(1) Transform an article or physical object to a different state or thing:**

Claims 1-9, 15-16 and 17-23 do not provide a transformation or reduction of an article to a different state or thing.

If no transformation, then;

**(2) The claimed invention must produce a useful, concrete, and tangible result.**

Accordingly, one must then consider whether the claimed invention produces a useful, concrete, and tangible result.

**(2-1) Useful Result**

For an invention to be “useful” it must satisfy the utility requirement of section 101. The USPTO’s official interpretation of the utility requirement provides that the utility of the invention has to be (i) specific, (ii) substantial and (iii) credible. See MPEP 2107. It can be argued that the claims do not provide a useful result in that the claim does not actually solve a problem.

Simple computing and deriving with no result thereafter does not appear to be useful.

**(2-2) Tangible Result**

The tangible requirement does not necessarily mean that a claim must either be tied to a particular machine or apparatus or must operate to change articles or materials to a different state or thing. However, the tangible requirement does require that the claim must recite more than a 101 judicial exception, in that the process claim must set forth a practical application of that 101 judicial exception to produce a real world result.

Regarding the tangible result requirement, the claims clearly do not provide a practical application for reasons similar to that discussed above. For example, once the pressure is calculated, how is this then applied?

### **(2-3) Concrete Result**

Another consideration is whether the invention produces a “concrete” result. Usually, this question arises when a result cannot be assured. In other words, the process must have a result that can be substantially repeatable or the process must substantially produce the same result again. Resolving this question is dependent on the level of skill in the art. For example, if the claimed invention is for a process, which requires a particular skill, to determine whether the process is substantially repeatable will necessarily require a determination of the level of skill of the ordinary skilled artisan.

Claims 1-9,15-16 & 17-23 appear to meet the concrete result requirement.



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In view of the above analysis, applicant's claims 1-9,15-16 & 17-23 are a process, which includes a judicial exception therein. Upon review of the claim as a whole, there is no transformation nor does the claim produce a useful, and tangible result. Accordingly, the claim is non-statutory under 35 U.S.C. 101.

8. Claim 2, refers to a computer driven analyzing means, and claim 3 refers to an equation. The claims fail to recite that the instructions are computer executable, and further the instructions do not yield useful and tangible result.

Claims 2 & 3 are dependent on claim1, and since they are further limiting the scope of claim 1, therefore claim 1 is also Non-statutory under 35 U.S.C 101 as not having useful and tangible result.

11. Claims 17-23 is related to an algorithm, the same argument is also true for these claims, and no structure has been associated to the algorithm, neither the nature of it has been described and claimed.

### ***Claim Rejections - 35 USC § 102***

12. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

13. Claims 1-16 & 24-25 are rejected under 35 U.S.C. 102(b) as being anticipated by US Pat. No. 4,710,164 to Levin et al (Levin).

In ref to claims 1 & 10 & 24 & 25:

A detection device (Fig. 1) for detecting irregular intravascular pressure, said device comprising analyzing means (10) for automatically analyzing blood pressure upstream of a suspected location of irregular blood flow and comparing the blood pressure to a standard (Abstract & Col. 1, lines 54-68), whereby variations in the blood pressure during multiple tests is indicative of irregular blood flow.

In ref to claims 2 & 3:

The analyzing means is computer driven (hemodialysis machine 16, Col. 1, line 59) or an equation (A program on the microprocessor 10).

In ref to claim 4:

The equation is an algorithm (programmed microprocessor) that estimates pressure inside a blood access site, thereby detecting irregular blood flow (Col. 1, lines 54-68).

In ref to claims 15 & 16:

A system for providing warning of potential health problems due to irregular intravascular pressure (Col. 2, lines 1-6), said system comprising: a detection device (Fig. 1); and communication means (cable /electronic communication for connecting the display to the dialysis machine) operably connected to said

device for communicating a warning when said device indicates an irregularity of blood pressure of at least two uses of said device (Col. 4, lines 18-22).

In ref to claims 11 & 14:

The calculating step includes automatically calculating blood pressure (10 & 14, Col. 3, lines 47-52), during a procedure (Col. 4, lines 67-68 & Col. 5, lines 1-2).

In ref to claim 12:

The comparing step includes automatically comparing the blood pressure to a standard (Col. 4, lines 47-55).

In ref to claim 13:

The automatically comparing step further includes automatically comparing the blood pressure to a standard using an algorithm (Col. 4, lines 46-47, microprocessor is programmed).

***Conclusion***

14. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. US Pat. No. 4,531,941 to Zasuwa, US Pat. No. 5,873,835 to Hastings et al, US Pat. No. 4,735,212 to Cohen, US Pat. Pub. No. 2007/0016084 to Danault and US Pat. No. 6,579,241 to Rocher; have been cited because they disclose a

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method and apparatus for automatically administering blood, by measuring blood pressure.

15. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anita Saidi whose telephone number is 571-270-3001. The examiner can normally be reached on Monday-Thursday 8:30 am - 7:00 pm Est..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kenneth Bomberg can be reached on 571-272-4922. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

16. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

6/14/2007 AS



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